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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,667	10/18/2001	James R. Prudent	FORS-06638	7631
23535	7590	06/04/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			SIEW, JEFFREY	
		ART UNIT		PAPER NUMBER
		1637		

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/982,667

**Applicant(s)**

PRUDENT ET AL.

**Examiner**

Jeffrey Siew

**Art Unit**

1637

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 02 February 2004.  
2a) This action is **FINAL**.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 26-35,42,61-76 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 26-35,42,61-76 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on 18 October 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Information Disclosure Statement***

1. The information disclosure statement filed 1/22/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The response's argument filed 2/2/04 has been fully considered and deemed persuasive. However, a copy of the I.D.S. unfortunately has not been properly scanned and is missing from the application. The office respectfully requests a courtesy copy of the I.D.S. filed January 22, 2003.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-35,42 & 61-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 26-35,42 & 61-76 are indefinite because the language in claim 26 does not clearly describe the cleavage structure formed. The claim recites that the second nucleic acid has 5' portion that is completely complementary to second portion. It is unclear as to whether the 5' is hybridized partially or fully or at all to the region. Similarly the language of the first nucleic acid is unclear. It is unclear as to whether there are three separate nucleic acids or they represent different portions.

The response states that the cleavage structure is clearly described. The response points to several locations in the specification (e.g. Figures 16A,16C-16E). However these figures do not denote three separate nucleic acids as required in the claims. One of skilled in the art would not clearly determine the metes and bounds of the instant claim. The limitations of the specification are not read into the claims. It is still unclear as to what cleavage structure would be formed.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-29,33,42,61-63 & 65-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyamichev et al (Science vol. 260:778-783 1993).

Lyamichev et al teach a structure specific endonucleolytic cleavage of single stranded DNA or RNA at bifurcated end of a DNA duplex wherein cleavage is not coupled to synthesis (abstract). Figure 1A demonstrates the cleavage of DNA hairpin by DNAP-Taq. The figure further teaches incubation of cleavage reaction at 72C and 55C. They teach the molecule is generated by PCR (see Figure 1 note). They use alpha 32P label (see Figure 4). They teach two types of oligonucleotides , one in which 3' portion is partially complementary and one in which the 3' portion is completely complementary (see figure 6a). Lyamichev teach three essential components, a substrate strand, primer duplex and a substrate duplex.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30, 32 & 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyamichev et al (Science vol. 260:778-783 1993) in view of Mergny et al (NAR vol. 22 No.6 pp. 920-928).

The teachings of Lyamichev et al are described previously.

Lyamichev et al does not teach fluorescence energy transfer.

Mergny et al teaches fluorescence energy transfer as a probe (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Mergny et al's fluorescence energy transfer to Lyamichev et al's nucleic acid in order to increase the detection efficiency. The use of fluorescence energy transfer labels avoids the use of radioactivity and increases detection. It would have been *prima facie* obvious to apply Mergny et al's fluorescent labels to Lyamichev et al's method of detection in order to avoid the use of radioactivity and increase the detection efficiency.

## SUMMARY

5. No claims allowed.

## CONCLUSION

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew who can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (571)272-0534.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The 1600 Tech Center FAX is (703)-872-9306.

*Jeffrey Siew*  
**JEFFREY SIEW**  
**PRIMARY EXAMINER**

May 21, 2004